General

Guideline Title

Clinical practice guideline for the treatment of intrinsic circadian rhythm sleep-wake disorders: advanced sleep-wake phase disorder (ASWPD), delayed sleep-wake phase disorder (DSWPD), non-24-hour sleep-wake rhythm disorder (N24SWD), and irregular sleep-wake rhythm disorder (ISWRD). An update for 2015.

Bibliographic Source(s)

Auger RR, Burgess HJ, Emens JS, Deriy LV, Thomas SM, Sharkey KM. Clinical practice guideline for the treatment of intrinsic circadian rhythm sleep-wake disorders: advanced sleep-wake phase disorder (ASWPD), delayed sleep-wake phase disorder (DSWPD), non-24-hour sleep-wake rhythm disorder (N24SWD), and irregular sleep-wake rhythm disorder (ISWRD). An update for 2015. J Clin Sleep Med. 2015 Oct 15;11(10):1199-236. [200 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Morgenthaler TI, Lee-Chiong T, Alessi C, Friedman L, Aurora RN, Boehlecke B, Brown T, Chesson AL Jr, Kapur V, Maganti R, Owens J, Pancer J, Swick TJ, Zak R, Standards of Practice Committee of the American Academy of Sleep Medicine. Practice parameters for the clinical evaluation and treatment of circadian rhythm sleep disorders. An American Academy of Sleep Medicine report. Sleep. 2007 Nov 1;30(11):1445-59. [133 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The quality of evidence (High-Very Low) and strengths of recommendations (For, Against) are defined at the end of the "Major Recommendation" field.

Recommendations for Treatments of Intrinsic Circadian Rhythm Sleep-wake disorders (CRSWDs)

Recommendations for the Treatment of Advanced Sleep-Wake Phase Disorder (ASWPD)

Prescribed Sleep-wake Scheduling for Patients with ASWPD

There is insufficient evidence to support the use of prescribed sleep-wake scheduling as a treatment for patients with ASWPD (versus no treatment). No recommendation.

Timed Physical Activity/Exercise for Patients with ASWPD

There is no evidence to support the use of timed physical activity or exercise as a treatment for patients with ASWPD. No recommendation.

Strategic Avoidance of Light for Patients with ASWPD

There is no evidence to support the use of strategic avoidance of light as a treatment for patients with ASWPD. No recommendation.

Light Therapy for Patients with ASWPD

The Task Force (TF) suggests that clinicians treat adult ASWPD patients with evening light therapy (versus no treatment). [WEAK FOR]

Sleep-promoting Medications for Patients with ASWPD

There is no evidence to support the use of sleep-promoting medications as a treatment for patients with ASWPD. No recommendation.

Timed Oral Administration of Melatonin or Agonists for Patients with ASWPD

There is no evidence to support the use of melatonin or agonists as a treatment for patients with ASWPD. No recommendation.

Wakefulness-promoting Medications for Patients with ASWPD

There is no evidence to support the use of wakefulness-promoting medications as a treatment for patients with ASWPD. No recommendation.

Other Somatic Interventions for Patients with ASWPD

There is no evidence to support the use of other somatic interventions as a treatment for patients with ASWPD. No recommendation.

Combination Treatments for Patients with ASWPD

There is no evidence to support the use of combination treatments for patients with ASWPD. No recommendation.

Recommendations for the Treatment of Delayed Sleep-Wake Phase Disorder (DSWPD)

Prescribed Sleep-wake Scheduling for Patients with DSWPD

There is insufficient evidence to support prescribed sleep-wake scheduling as a stand-alone treatment (versus no treatment) for patients with DSWPD. No recommendation.

Timed Physical Activity/Exercise for Patients with DSWPD

There is no evidence to support the use of timed physical activity or exercise as a treatment for patients with DSWPD. No recommendation.

Strategic Avoidance of Light for Patients with DSWPD

There is insufficient evidence to support the use of strategic avoidance of light as a treatment for patients with DSWPD (versus no treatment). No recommendation.

Light Therapy for Patients with DSWPD

There is insufficient evidence to support efficacy of post-awakening light therapy (monotherapy) as a treatment for DSWPD (versus no treatment). No recommendation.

Sleep-promoting Medications for Patients with DSWPD

There is insufficient evidence to support the use of sleep-promoting medications as a treatment for patients with DSWPD (versus no treatment). No recommendation.

Timed Oral Administration of Melatonin or Agonists for Patients with DSWPD

Melatonin for Adult Patients with DSWPD

The TF suggests that clinicians treat DSWPD in adults with and without depression with strategically timed melatonin (versus no treatment). [WEAK FOR]

Melatonin for Children/Adolescents with DSWPD

> The TF suggests that clinicians treat children and adolescents with DSWPD (and no comorbidities) with strategically timed melatonin (versus no treatment). [WEAK FOR]
> The TF suggests that clinicians treat children and adolescents with DSWPD comorbid with psychiatric conditions with strategically timed melatonin (versus no treatment). [WEAK FOR]

Wakefulness-promoting Medications for Patients with DSWPD

There is no evidence to support the use of wakefulness-promoting medications as a treatment for patients with DSWPD. No recommendation.

Other Somatic Interventions for Patients with DSWPD

There is insufficient evidence to support the use of oral vitamin B12 (and no evidence to support alternate somatic interventions) among patients with DSWPD (versus no treatment). No recommendation.

Combination Treatments for Patients with DSWPD

Light/Combination Treatments for Adults with DSWPD

There is insufficient evidence to support the use of novel forms of light therapy (i.e., via means other than a "light box"), in association with concomitant behavioral instructions among adults with DSWPD (versus no treatment). No recommendation.

Light/Combination Treatments for Children/Adolescents with DSWPD

The TF suggests that clinicians treat children and adolescents with DSWPD with post-awakening light therapy in conjunction with behavioral treatments (versus no treatment). [WEAK FOR]

Recommendations for the Treatment of Non-24-Hour Sleep-Wake Rhythm Disorder (N24SWD)

Prescribed Sleep-wake Scheduling for Patients with N24SWD

There is no evidence to support the use of prescribed sleep-wake scheduling in patients with N24SWD. No recommendation.

Timed Physical Activity/Exercise for Patients with N24SWD

There is no evidence to support the use of timed physical activity or exercise in patients with N24SWD. No recommendation.

Strategic Avoidance of Light for Patients with N24SWD

There is no evidence to support the use of strategic avoidance of light (as monotherapy) in patients with N24SWD. No recommendation.

Light Therapy for Patients with N24SWD

There is insufficient evidence to support the use of light therapy in patients with N24SWD (versus no treatment). No recommendation.

Sleep-promoting Medications for Patients with N24SWD

There is no evidence to support the use of sleep-promoting medications in patients with N24SWD. No recommendation.

Timed Oral Administration of Melatonin or Agonists for Patients with N24SWD

Melatonin for Blind Adult Patients with N24SWD

The TF suggests that clinicians use strategically timed melatonin for the treatment of N24SWD in blind adults (versus no treatment). [WEAK FOR]

Melatonin for Sighted Patients with N24SWD

There is insufficient evidence to support the use of melatonin among sighted patients with N24SWD (versus no treatment). No recommendation.

Wakefulness-promoting Medications for Patients with N24SWD

There is no evidence to support the use of wakefulness-promoting medications in patients with N24SWD. No recommendation.

Other Somatic Interventions for Patients with N24SWD

There is insufficient evidence to support the use of oral vitamin B12 (and no evidence to support alternate somatic interventions) among patients with N24SWD (versus no treatment). No recommendation.

Combination Treatments for Patients with N24SWD

There is insufficient evidence to support the use of combination treatments in patients with N24SWD (versus no treatment). No recommendation.

Recommendations for the Treatment of Irregular Sleep-wake Rhythm Disorder (ISWRD)

Prescribed Sleep-wake Scheduling for Patients with ISWRD

There is no evidence to support the use of prescribed sleep-wake scheduling as a stand-alone treatment for patients with ISWRD. No recommendation.

Timed Physical Activity/Exercise for Patients with ISWRD

There is no evidence to support the use of timed physical activity or exercise as a stand-alone treatment for patients with ISWRD. No recommendation.

Strategic Avoidance of Light for Patients with ISWRD

There is no evidence to support the use of strategic avoidance of light as a treatment for patients with ISWRD. No recommendation.

Light Therapy for ISWRD in Elderly Patients with Dementia

The TF suggests that clinicians treat ISWRD in elderly patients with dementia with light therapy (versus no treatment). [WEAK FOR]

Sleep-promoting Medications for ISWRD in Elderly Patients with Dementia

The TF recommends that clinicians avoid the use of sleep-promoting medications to treat demented elderly patients with ISWRD (versus no treatment). [STRONG AGAINST]

Timed Oral Administration of Melatonin or Agonists for Patients with ISWRD

Melatonin for Elderly Patients with Dementia and ISWRD

The TF suggests that clinicians avoid the use of melatonin as a treatment for ISWRD in older people with dementia (versus no treatment). [WEAK AGAINST]

Melatonin in Children/Adolescents with ISWRD and Neurologic Disorders

The TF suggests that clinicians use strategically timed melatonin as a treatment for ISWRD in children/adolescents with neurologic disorders (versus no treatment). [WEAK FOR]

Wakefulness-promoting Medications for Patients with ISWRD

There is no evidence to support the use of wakefulness-promoting medications as a treatment for patients with ISWRD. No recommendation.

Other Somatic Interventions for Patients with ISWRD

There is no evidence to support the use of other somatic interventions for the treatment of patients with ISWRD. No recommendation.

Combination Treatments in Demented Elderly Adults with ISWRD

The TF suggests that clinicians avoid the use of combined treatments consisting of light therapy in combination with melatonin in demented, elderly patients with ISWRD (versus no treatment). [WEAK AGAINST]

Combination Treatments for Children/Adolescents with ISWRD

There is insufficient evidence to support the use of combination treatments in children/adolescents with ISWRD (versus no treatment). No recommendation.

Definitions

Quality of a Body of Evidence

High: Corresponds to a high level of certainty that the true effect lies close to that of the estimate of the effect.

Moderate: Corresponds to a moderate level of certainty in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low: Corresponds to a low level of certainty in the effect estimate; the true effect may be substantially different from the estimate of the effect.

Very low: Corresponds to very little certainty in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

Definitions of American Academy of Sleep Medicine (AASM) Strengths of Recommendations

AASM Strength of Recommendation		Example Characteristics Guiding Recommendation
FOR	STRONG	There is a high degree of clinical certainty in the net benefits of this patient-care strategy. The vast majority of well-informed patients would most likely choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.
	WEAK	There is a lower degree of clinical certainty in the balance between benefits vs. harms (e.g., net benefits) of this patient-care strategy. The majority of well-informed patients would most likely choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.
AGAINST	WEAK	There is a lower degree of clinical certainty in the balance between benefits vs. harms (e.g., net harms) of this patient-care strategy. The majority of well-informed patients would most likely not choose this patient-care strategy, compared to alternative patient-care strategies or no

AASM Strength of Recommendation		Example Characteristics Guiding Recommendation
	STRONG	There is a high degree of clinical certainty in the net harms of this patient-care strategy. The vast majority of well-informed patients would most likely not choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Intrinsic circadian rhythm sleep-wake disorders (CRSWDs):

- Advanced sleep-wake phase disorder (ASWPD)
- Delayed sleep-wake phase disorder (DSWPD)
- Non-24-hour sleep-wake rhythm disorder (N24SWD)
- Irregular sleep-wake rhythm disorder (ISWRD)

Note: The extrinsic or predominantly environmentally influenced CRSWDs, namely shift work and jet lag disorder, are not addressed in this paper.

Guideline Category

Management

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Neurology

Psychiatry

Sleep Medicine

Intended Users

Physician Assistants

Physicians

Guideline Objective(s)

To provide an evidence-based update of existing recommendations for the treatment of the *intrinsic* circadian rhythm sleep-wake disorders (CRSWDs): advanced sleep-wake phase disorder (ASWPD), delayed

sleep-wake phase disorder (DSWPD), non-24-hour sleep-wake rhythm disorder (N24SWD), and irregular sleep-wake rhythm disorder (ISWRD)

Target Population

Patients diagnosed with intrinsic circadian rhythm sleep-wake disorders (CRSWDs) (advanced sleep-wake phase disorder [ASWPD], delayed sleep-wake phase disorder [DSWPD], non-24-hour sleep-wake rhythm disorder [N24SWD], and irregular sleep-wake rhythm disorder [ISWRD])

Interventions and Practices Considered

1. Light therapy
    - Evening
    - Post-awakening in conjunction with behavioral treatment
2. Strategically timed melatonin (as indicated)
3. Light therapy and melatonin combination (not recommended for demented, elderly patients)

Major Outcomes Considered

- Physiologic circadian phase markers
- Total sleep time (TST)
- Initial sleep latency (ISL)
- Sleep onset time (SOT)
- Sleep offset time (SOffT)
- Adverse effects of medications
- Quality of life
- Entrainment status (non-24-hour sleep-wake rhythm disorder [N24SWD] only)

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Searches

Literature search #1 was performed in PubMed using broad terms (see the Appendix in the original guideline document), in order to identify systematic reviews, meta-analyses or relevant practice guidelines published subsequent to availability of the previous American Academy of Sleep Medicine (AASM) Practice Parameters. Examination of discovered papers (n=93) enabled elucidation of Practice Parameter recommendations requiring revisions, and also assisted with further refinement of the Patient, Population or Problem, Intervention, Comparison, and Outcomes (PICO) questions. Results from literature search #1 were not included in the systematic review and thus did not contribute to the recommendations in this guideline: the resulting literature was gathered for instructive purposes only, to help determine which recommendations warranted updating.

The next literature search (#2) targeted treatment trials involving intrinsic circadian rhythm sleep-wake

disorders (CRSWDs) that addressed at least one PICO question. This search utilized PubMed, EMBASE, and PsycINFO databases. Literature search #2 was conducted in July 2012, and searched for literature published from October 2006 through July 2012.

At least two Task Force (TF) members carefully assessed the abstract of each retrieved article (n=2,063), to determine whether the publication should be included for further consideration. The following list of general exclusion criteria was used:

Diagnosis or not treatment
CRSWD
Not intrinsic CRSWD (shift work or jet-lag disorder)
Wrong publication type (review, editorial, etc.)
Not human subjects
Mechanistic or methodological study
Study was published before October 2006

When there were questions or disagreements, the full text of the article was reviewed in detail until consensus was reached. The same search terms, databases and inclusion/exclusion criteria were used for literature search #3, although new date limitations were applied (June, 2012–March, 2014), with the intention to capture articles published after completion of search #2. Four hundred fifty-three additional publications were retrieved, and TF assessments occurred in the same manner described above. Finally, TF members selected several literature reviews (by consensus), and screened reference lists to identify other articles of potential interest. This "pearling" process served as a "spot control" for the previous searches, and ensured that important articles were not missed. All duplicate references were eliminated.

Since new inclusion/exclusion criteria were used in this project, investigations cited in the previous Practice Parameters were not necessarily incorporated into the current analysis. Studies that did not meet inclusion criteria were selectively used for discussion purposes, but were neither included in the Grading of Recommendations Assessment, Development and Evaluation (GRADE) reports nor used as a basis for recommendations. The TF made a particular effort to discuss those studies (containing either patients or healthy subjects) that might spur and/or improve future clinical research for the reviewed CRSWDs.

A final PubMed search was conducted to identify harms or adverse effects attributed to the relevant interventions: light therapy (PICO 4), hypnotics (PICO 5), and melatonin (PICO 6) (see the Appendix in the original guideline document). Limitations were imposed to select for English-language "meta-analyses" and "systematic reviews" pertaining to human subjects. The titles and abstracts of articles produced by these searches were reviewed for relevance, and pertinent publications were examined. Other cited articles from the "Harms and Adverse Effects" section in the original guideline document were culled from prior searches (but deemed ineligible for quantitative analysis) or were provided via TF members' preemptive awareness and consensus regarding relevancy. Adverse effects of combined treatments were addressed based on the singular components of combinations.

Number of Source Documents

The recommendations are based on an evidence base of 53 studies.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of a Body of Evidence

High: Corresponds to a high level of certainty that the true effect lies close to that of the estimate of the

effect.

Moderate: Corresponds to a moderate level of certainty in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low: Corresponds to a low level of certainty in the effect estimate; the true effect may be substantially different from the estimate of the effect.

Very low: Corresponds to very little certainty in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

Methods Used to Analyze the Evidence

Meta-Analysis

Systematic Review

Description of the Methods Used to Analyze the Evidence

Extraction of Evidence

Quantitative data pertaining to the outcomes of interest as well as information necessary for systematic evaluation and grading of the evidence were extracted from accepted articles using a dedicated spreadsheet. Articles determined to lack quantitative data or with data presented in a format incompatible with desired statistical analyses were rejected at this stage, but used selectively for further discussion. In instances where desired data were available but not presented in the desired format, the authors were contacted, and raw data were acquired if possible. Data were pooled across the studies for each outcome measure in accordance with Population, Intervention, Comparison, and Outcome (PICO) questions and based on diagnosis, study design, patient population, clinical outcome of interest, and method of derivation (e.g., polysomnography [PSG] derived data were analyzed separately from data derived from actigraphy or sleep diaries).

Statistical Analyses

Meta-analyses were completed (in the few instances possible) using the random effects model. All computations were performed using the Review Manager software, and included calculations of the mean difference (MD) ± standard deviation (SD) for CRITICAL outcomes. Values analyzed in this manner are displayed to the hundredths place. Age demographics and information regarding melatonin doses are presented in the format provided by the associated study (mean ± SD if available) but, in an effort to maintain consistency, are displayed only to the tenths place in instances where the authors provided values with numerical place values of lower hierarchy. The results of meta-analyses are depicted in figures within the text, in association with a "forest plot." Summary of findings tables for all investigations are presented in the Appendix in the original guideline document.

When studies contained placebo/control groups, the evaluation of the effect of treatment was performed by comparison of averaged posttreatment and averaged post-placebo/control group values, regardless of the authors' approaches. In studies with crossover or "before-after" designs where there was no placebo/control group, posttreatment values were compared to baseline values. Our use of this methodology occasionally produced results that differed from those reported in the original publications.

Quality of Evidence

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach was used for the assessment of quality of evidence (see the "Rating Scheme for the Strength of the Evidence" field). In contrast to other methods, an estimate of effect is generated for critical outcomes across studies, as opposed to an evaluation of individual studies. Multiple aspects of quality of evidence are assessed, with downgrading of evidence as applicable (see Table 3 in the original guideline document).

The body of evidence for each outcome was assessed and graded, taking into account quality considerations based on the quantitative analysis and other major factors described above. CRITICAL outcome results are presented as summary of findings tables organized by PICO question and patient population (see the Appendix [Tables S1–S12] in the original guideline document).

A cumulative quality grade for a particular PICO question and patient population is predicated upon the *lowest* level of evidence assigned to one of the CRITICAL outcomes. Thus, if a recommendation was based upon two outcomes, one of moderate and one of low quality, the overall grade would be low.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Expert Task Force

In order to develop these Clinical Practice Guidelines, the American Academy of Sleep Medicine (AASM) commissioned a Task Force (TF) of four members with expertise in the field of circadian rhythm sleep-wake disorders (CRSWDs), appointed an AASM Board of Directors (BOD) liaison, and assigned an AASM Science and Research Department staff member to manage the project. The Task Force performed an extensive review of the scientific literature and assessed the available evidence employing the methodology of evidence-based medicine (specifically, meta-analysis and the Grading of Recommendations Assessment, Development and Evaluation system [GRADE]) to draft recommendations.

PICO Questions

Eight PICO (Population, Intervention, Comparison, and Outcome) questions were developed, based on both the inquiries raised in the previous AASM publications and an investigation of systematic reviews, meta-analyses, and guidelines published subsequently (see Table 1 in the original guideline document). The AASM BOD ultimately approved these questions. In addition, combination treatments were also reviewed for the four intrinsic CRSWDs included in this guideline.

Strength of Recommendations

The TF developed recommendation statements and determined the strengths of these recommendations based on the balance of the following major factors:

- Level of evidence—based on an assessment of the quality of evidence using GRADE criteria (see Table 3 in the original guideline document), the TF categorized the evidence as:
  - High
  - Moderate
  - Low
  - Very Low
- Benefits vs. Harms—based upon CRITICAL outcomes and analysis of any harms/side effects, the TF assessed whether:
  - Benefits outweighed harms
  - Benefits equaled harms
  - Harms outweighed benefits
  - The balance between benefits and harms was unclear
- Patient values and preferences—based on the clinical expertise of the TF and relevant published data, including discussion in the referenced papers about tolerability, compliance, and patients' experiences with the treatments in question, the TF judged whether:
  - The vast majority of well-informed patients (>90%) would most likely use this patient-care strategy, compared to alternative patient-care strategies or no treatment
  - The majority of well-informed patients would most likely use this patient-care strategy,

compared to alternative patient-care strategies or no treatment
The majority of well-informed patients would most likely NOT use this patient-care strategy, compared to alternative patient-care strategies or no treatment
The vast majority of patients (>90%) would most likely NOT use this patient-care strategy, compared to alternative patient-care strategies or no treatment

Taking these variables into consideration, each recommendation statement was given a "strength value" of Strong For, Weak For, Weak Against or Strong Against (see the "Rating Scheme for the Strength of the Recommendations" field). As an example, a body evidence could be rated VERY LOW, while another could be rated MODERATE, and yet both could generate a WEAK FOR recommendation, based upon the above mentioned factors.

There were multiple cases when the TF chose to make "No Recommendation," which reflects either a complete lack of available evidence (no studies were published) or situations when evidence was available but either did not meet review inclusion criteria or was considered insufficient to support a recommendation (see the Appendix [Tables S5 and S6] in the original guideline document). It needs to be emphasized that "No Recommendation" does not mean that treatments should not be tried but that, in the absence of sufficient and conclusive evidence, clinicians should use their best judgment to decide in each particular case whether or not a treatment should be used. At the step of review of the extracted evidence, the TF made a decision to exclude studies with fewer than 10 subjects if the study constituted a single source of evidence, as it was felt that affiliated data were insufficient to support a recommendation.

Rating Scheme for the Strength of the Recommendations

Definitions of American Academy of Sleep Medicine (AASM) Strengths of Recommendations

AASM Strength of Recommendation		Example Characteristics Guiding Recommendation
FOR	STRONG	There is a high degree of clinical certainty in the net benefits of this patient-care strategy. The vast majority of well-informed patients would most likely choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.
	WEAK	There is a lower degree of clinical certainty in the balance between benefits vs. harms (e.g., net benefits) of this patient-care strategy. The majority of well-informed patients would most likely choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.
AGAINST	WEAK	There is a lower degree of clinical certainty in the balance between benefits vs. harms (e.g., net harms) of this patient-care strategy. The majority of well-informed patients would most likely not choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.
	STRONG	There is a high degree of clinical certainty in the net harms of this patient-care strategy. The vast majority of well-informed patients would most likely not choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

The original guideline document was approved by the American Academy of Sleep Medicine Board of Directors (AASM BOD) and replaces the previous Practice Parameters.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- This update should provide clinicians with heightened confidence with respect to prescribing select treatments and, equally importantly, should serve as a roadmap for future studies that will propel higher quality, more sophisticated therapies for the intrinsic circadian rhythm sleep-wake disorders (CRSWDs).
- See also Table 6 in the original guideline document for a benefits/harms assessment of specific recommendations.

Potential Harms

- See the "Harms and Adverse Effects" section in the original guideline document for a discussion of adverse effects of light therapy, melatonin and hypnotics.
- See Table 6 in the original guideline document for a benefits/harms assessment of specific recommendations.
- Melatonin has been associated with an increase in depressive symptoms, and caution is advised when prescribing to patients taking warfarin and to patients with epilepsy, as a result of various case reports submitted to the World Health Organization (WHO).

Qualifying Statements

Qualifying Statements

- The American Academy of Sleep Medicine (AASM) expects these guidelines to have a positive impact on clinical decision making and patient outcomes. These recommendations reflect the state of knowledge at the time of publication and will be revised when the availability of new information necessitates.
- This publication should serve as an impetus to address clinical research deficiencies and to promote

novel inquiries for treatments of these challenging and interesting conditions.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Auger RR, Burgess HJ, Emens JS, Deriy LV, Thomas SM, Sharkey KM. Clinical practice guideline for the treatment of intrinsic circadian rhythm sleep-wake disorders: advanced sleep-wake phase disorder (ASWPD), delayed sleep-wake phase disorder (DSWPD), non-24-hour sleep-wake rhythm disorder (N24SWD), and irregular sleep-wake rhythm disorder (ISWRD). An update for 2015. J Clin Sleep Med. 2015 Oct 15;11(10):1199-236. [200 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2015 Oct 15

Guideline Developer(s)

American Academy of Sleep Medicine - Professional Association

Source(s) of Funding

This was not an industry supported study.

Guideline Committee

Expert Task Force

Composition of Group That Authored the Guideline

Task Force (TF) Members: R. Robert Auger, MD, Mayo Center for Sleep Medicine, Rochester, MN; Helen J. Burgess, PhD, Rush University Medical Center, Chicago, IL; Jonathan S. Emens, MD, Portland VA Medical Center, Portland, OR; Ludmila V. Deriy, PhD, American Academy of Sleep Medicine, Darien, IL; Sherene M. Thomas, PhD, American Academy of Sleep Medicine, Darien, IL; Katherine M. Sharkey, MD, PhD, Brown University, Providence, RI

Financial Disclosures/Conflicts of Interest

Prior to appointment, the content experts were required to disclose all potential conflicts of interest according to American Academy of Sleep Medicine (AASM) policy. None were declared.

Disclosure Statement

The authors have indicated no financial conflicts of interest. Drs. Deriy and Thomas are employed by the American Academy of Sleep Medicine.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Morgenthaler TI, Lee-Chiong T, Alessi C, Friedman L, Aurora RN, Boehlecke B, Brown T, Chesson AL Jr, Kapur V, Maganti R, Owens J, Pancer J, Swick TJ, Zak R, Standards of Practice Committee of the American Academy of Sleep Medicine. Practice parameters for the clinical evaluation and treatment of circadian rhythm sleep disorders. An American Academy of Sleep Medicine report. Sleep. 2007 Nov 1;30(11):1445-59. [133 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the American Academy of Sleep Medicine (AASM) Web site .

Availability of Companion Documents

Continued medical education (CME) credit is available from the Journal of Clinical Sleep Medicine Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on April 11, 2008. This summary was updated by ECRI Institute on May 1, 2009 following the U.S. Food and Drug Administration advisory on antiepileptic drugs. This summary was updated by ECRI Institute on January 26, 2016. The updated information was verified by the guideline developer on February 24, 2016.

Copyright Statement

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